

UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE United States Patent and Trademark Office Address COMMISSIONER FOR PATENTS F O Box 1450 Alexandria, Virginia 22313-1450 www.uspilo.gov

LIPPE EGLETON NO.	THE DAY IN A THE	FIRST NAMED INVENTOR	LITTONITY DOGUTE VO	CONTROLLETONING
APPLICATION NO. 09/982,548	FILING DATE 10/18/2001		M0656,70070US00	CONFIRMATION NO. 7782
09/982,348	10/18/2001	Dongfang Liu	M0030,70070US00	7782
28628 WOLF GREENFIELD & SACKS, P.C. 600 ATLANTIC AVENUE			EXAMINER	
			MCINTOSH III, TRAVISS C	
BOSTON, MA 02210-2206			ART UNIT	PAPER NUMBER
			1623	
			MAIL DATE	DELIVERY MODE
			03/17/2008	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Application No. Applicant(s) 09/982 548 LIU ET AL. Office Action Summary Examiner Art Unit TRAVISS C. MCINTOSH III 1623 -- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --Period for Reply A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS. WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION. Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication. If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication. Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b). Status 1) Responsive to communication(s) filed on 06 December 2007. 2b) This action is non-final. 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under Ex parte Quayle, 1935 C.D. 11, 453 O.G. 213. Disposition of Claims 4)\(\times\) Claim(s) 58.116-121.204.206-209.211-213.223-232 and 238-252 is/are pending in the application. 4a) Of the above claim(s) 232 and 238 is/are withdrawn from consideration. 5) Claim(s) 58.116-121.204.206-209.211-213 and 223-231 is/are allowed. 6) Claim(s) 239-252 is/are rejected. 7) Claim(s) ____ is/are objected to. 8) Claim(s) ____ are subject to restriction and/or election requirement. Application Papers 9) The specification is objected to by the Examiner. 10) The drawing(s) filed on is/are; a) accepted or b) objected to by the Examiner. Applicant may not request that any objection to the drawing(s) be held in abevance. See 37 CFR 1.85(a). Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d). 11) The oath or declaration is objected to by the Examiner, Note the attached Office Action or form PTO-152. Priority under 35 U.S.C. § 119 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f). a) ☐ All b) ☐ Some * c) ☐ None of: Certified copies of the priority documents have been received. 2. Certified copies of the priority documents have been received in Application No. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)). * See the attached detailed Office action for a list of the certified copies not received. Attachment(s)

U.S. Patent and Trademark Office PTOL-326 (Rev. 08-06)

1) Notice of References Cited (PTO-892)

Notice of Draftsberson's Fatent Drawing Serview (PTC-946)

Information Disclosure Statement(s) (PTO/SB/08)
 Paper No(s)/Mail Date ______.

Interview Summary (PTO-413)
 Paper No(s)/Mail Date.

6) Other:

5) Notice of Informal Patent Application

DETAILED ACTION

The Amendment filed 12/6/2007 has been received, entered into the record, and carefully considered. The following information provided in the amendment affects the instant application by:

Claims 58, 116-121, 204, 206-209, 211-213, and 223-232 have been amended.

Claims 239-252 have been added

Claims 1-57, 59-115, 122-203, 205, 210, 214-222 and 233-237 have been canceled.

Remarks drawn to rejections of Office Action mailed 6/1/2007 include:

Claim objections: which have been overcome by applicant's amendments and have been withdrawn.

112 2nd paragraph rejections: which have been overcome by applicant's amendments and have been withdrawn

102(b) rejection: which has been withdrawn over the rejected claims as they have been canceled, however, a new rejection has been made over the newly added claims as set forth below.

An action on the merits of claims 58, 116-121, 204, 206-209, 211-213, 223-232, and 238-252 is contained herein below. The text of those sections of Title 35, US Code which are not included in this action can be found in a prior Office action.

Application/Control Number: 09/982,548 Page 3

Art Unit: 1623

Election/Restrictions

Claims 232, 237, and 238 were previously withdrawn as being drawn to a non-elected group based upon original presentation. Applicants argued that their elected group II included methods of using the compositions of claims 43, 58, 116-121, and 204-214 and thus believes that claims 232, 237, and 238 are directed to such methods and thus should be included within the elected group. This is not found convincing. It is noted that the examiner restricted between groups I and II on 12/29/2005 and applicants elected group II on 5/5/06, which was treated as election without traverse as set forth in the office action on 8/8/2006. The subject matter of currently pending claims 232 and 238 belonged to the methods as set forth in group I of the restriction requirement: "drawn to methods of producing a therapeutic effect by administering HLGAG particles having a diameter of 1-500 microns". As such, claims 232 and 238 are withdrawn as being drawn to a non-elected group.

Claim Rejections - 35 USC § 102

Claims 239-252 are rejected under 35 U.S.C. 102(b) as being anticipated by Edelman et al. (US 5,527,532).

The '532 patent discloses dry unformulated heparin particles having a diameter of less that 180 microns (see sentence bridging columns 6-7). Since the Office does not have the facilities for preparing the claimed materials and comparing them with prior art inventions, the burden is on Applicant to show a novel or unobvious difference between the claimed product and the product of the prior art. See In re Best, 562 F.2d 1252, 195 USPQ 430 (CCPA 1977) and In re Fitzgerald et al., 619 F.2d 67, 205 USPO 594 (CCPA 1980). It is noted that the particles made

Application/Control Number: 09/982,548

Art Unit: 1623

by the '532 patent would be seen to have inherently contained particles which would have met the limitations instantly claimed.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action

Any inquiry concerning this communication or earlier communications from the examiner should be directed to TRAVISS C. MCINTOSH III whose telephone number is (571)272-0657. The examiner can normally be reached on M-F 9:30-6:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Shaojia A. Jiang can be reached on 571-272-0627. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Art Unit: 1623

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Traviss McIntosh March 3, 2008 Shaojia A. Jiang Supervisory Patent Examiner Art Unit 1623

/Shaojia Anna Jiang/ Supervisory Patent Examiner, Art Unit 1623